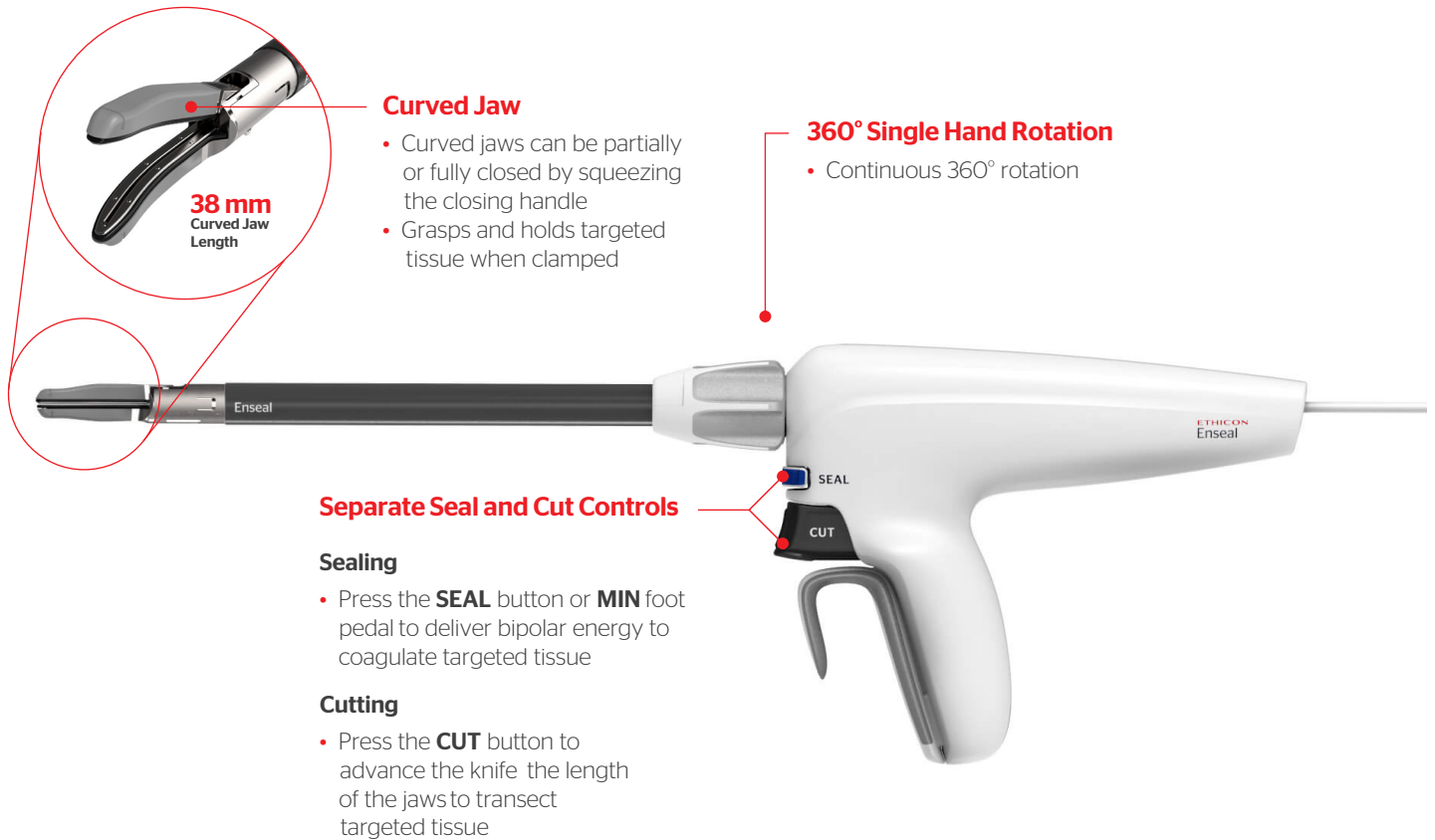


ENSEAL® X1 Large Jaw Tissue Sealer Optimized Device Performance

ENSEAL® X1 Large Jaw Tissue Sealer instrument is a dedicated bipolar electro-surgical instrument intended for use in open surgical procedures where ligation and division of vessels is desired. It is a bipolar instrument for use with the Ethicon Generator G11 (GEN 11).

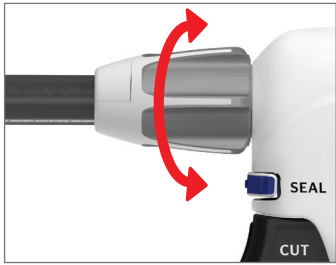
ENSEAL® X1 Technology:

- Cuts and seals vessels or cuts, grasps, and dissects tissue independently during surgery
- Coagulates and transects vessels, tissue, or vascular bundles up to and including 7 mm in diameter



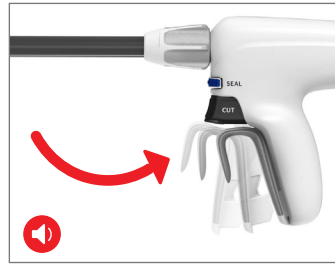
Tone	Description	Action
Activation Tone	Continuous steady beeping	Generator On: Device is active
End Tone	One short beep	End of Cycle: Energy is stopped

Optimal Usage



1. Rotate Knob

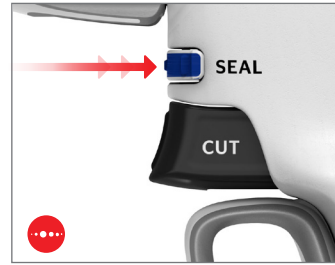
Turn the rotation knob to move the shaft around to the desired position. Position the vessel or tissue in the center of the jaws.



2. Close the Jaws

Squeeze closing handle until it latches (and a click is heard) to clamp targeted tissue between the jaws.

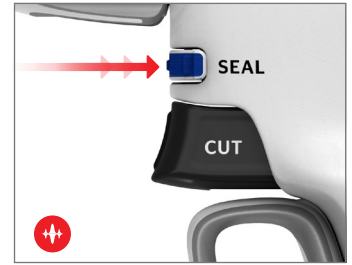
Warning:
If the closing handle is not fully latched, this may result in improper sealing and thermal spread.



3a. Seal (Activation - Tone 1)

Press the blue SEAL button or MIN foot pedal to energize the jaws and begin coagulation of the targeted tissue. The generator gives audible feedback (ActivationTone) as energy is delivered to the clamped tissue.

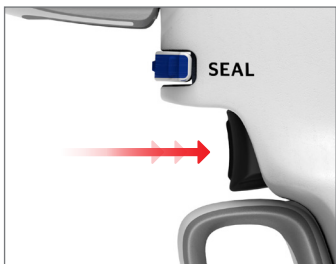
Warning:
To reduce the possibility of an inadvertent activation of the sealing mechanism, do not place your finger on the blue SEAL button until the jaws are in the desired position and activation is intended.



3b. Seal (End Tone - Tone 2)

Continue to depress the blue SEAL button or MIN foot pedal until the activation cycle is complete, and a second tone (End Tone) is heard, indicating energy has been stopped.

Caution:
Do not press the CUT button until the End Tone is heard. If the knife is advanced prior to the End Tone, this may result in an incomplete seal and lack of hemostasis.



4. Cut

Fully press the CUT button against the grip housing. The knife will advance to the cut line.

Warning:
To reduce the possibility of an inadvertent activation of the cutting mechanism prior to sealing, do not place your finger on the CUT button until activation is complete and transection is intended.



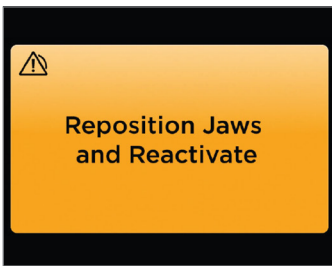
5. Open Jaws

After the transection cycle is complete, squeeze the closing handle until it unlocks.

Additional Warnings & Cautions

- 1 Use caution during surgical cases in which patients have connective tissue disorder or exhibit certain types of pathology (e.g., Atherosclerosis, Crohn's, etc.). For best results, apply the seal to unaffected vasculature.
- 2 Do not use energy-based devices to transect seals, such as electrocautery pencils or ultrasonic scalpels.
- 3 Do not use this device on vessels in excess of 7 mm in diameter. This may lead to improper sealing and hemostasis.
- 4 Pools of conductive fluids (e.g. blood, saline) in direct contact with the instrument jaws may affect device performance. Remove pooled fluid from around the instrument jaws before activating the instrument.

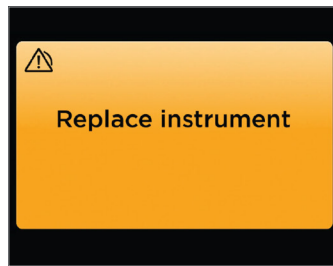
Generator Troubleshooting



Reposition Jaws and Reactivate

Description: "Short Detected" screen exits.

Troubleshooting: Reposition device and reactivate the SEAL button.



Replace Instrument

Description: The same alarm has triggered three times in a row. There may be an issue in the instrument.

Troubleshooting: Replace the instrument.

Cleaning the Device



Clean the Device

For optimal performance and to avoid tissue sticking, clean the instrument jaws and distal end of the shaft with a sterile, moist gauze sponge throughout the procedure.



Do Not Immerse

Do not immerse distal tip in liquid, including saline solution, to clean. This may result in damage to the instrument.



Do Not Clean Instrument with Abrasives

If tissue is still visible in the clamp arm, use forceps to remove residue, taking care not to actuate the instrument.